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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,972	06/15/2000	Ada Goerlach-Graw	BMID 9941 US	8671

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	15

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,972	Applicant(s) GOERLACH-GRAW ET AL.	
	Examiner Bao-Thuy L. Nguyen	Art Unit 1641	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/1/02 & 10/21/02* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's responses filed on July 1, 2002 and October 21, 2002 have been received. Claims 27-42 have been canceled. Claims 25-26 are pending.

2. The text of those US codes not found in this office action may be found in a previous office action.

3. All rejections not reiterated herein below are withdrawn.

Claim Rejections - 35 USC § 112, second paragraph

4. Claims 15-26 are rejected under 25 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15 is confusing with respect to the recitation of "an impregnated conjugate" for reasons of record.

Claim 15 is also confusing with respect to the recitation of "a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label" for reasons of record.

Response to Arguments

5. Applicants argue that the impregnated conjugate comprises "a first bioaffine binding partner...and a first detectable label", and that the specification at page 1 and 9 provides full support for the term "an impregnated conjugate". It is noted that the term "an impregnated conjugate" means that the conjugate is impregnated not that the matrix is impregnated as argued. While it is true that the specification provides support for a matrix impregnated with a conjugate comprising "a first bioaffine binding partner...and a first detectable label", the specification does not provide support for a "impregnated conjugate". It is suggested that Applicants amend the claim by deleting the term "impregnated" or make clear that the matrix is impregnated and not the conjugate.

Applicants argue that claim 15 requires that the universal conjugate comprises "a second bioaffine binding partner...and a second detectable label", however, it is noted that claim 15 actually reads as follows "...a universal conjugate...comprises a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label", therefore, it is unclear whether the second bioaffine binding partner comprises a second label or if the second bioaffine binding partner is capable of binding to a first and second label. It is suggested that Applicants amend the claim as follows "...a universal conjugate...comprises a second bioaffine binding partner and a second detectable label, the second bioaffine binding partner is capable of a specific binding reaction with the first detectable label."

Claim Rejections - 35 USC § 103

6. Claims 15-17 and 20-23 are rejected under 35 USC 103(a) as being unpatentable over Fitzpatrick et al (US 5,451,504) in view of Decker et al (US 4,230,683) for reasons of record in paper no. 9.

7. Claims 18, 19 and 24-26 are rejected under 35 USC 103(a) as being unpatentable over Fitzpatrick in view of Decker as applied to claims 15-17 and 20-23 above, and further in view of Bernstein et al (US 5,824,268) for reasons of record in paper no. 9.

Response to Arguments

8. Applicant's arguments filed on July 1, 2002 and October 21, 2002 have been fully considered but are not deemed to be persuasive.

Applicants argue that Fitzpatrick differs from the instant invention because they do not teach an "impregnated conjugate" as required by claim 15, and that the Fitzpatrick fails to provide any motivation to form an element with an impregnated conjugate located upstream of the zone containing immobilized analyte that comprises a first bioaffine binding partner and a first detectable label. It is noted that because of the ambiguous nature of the term "an impregnated conjugate" in claim 15, it is not clear that the matrix of the instant claims is impregnated (i.e. loaded/saturated/soaked, etc.) with the conjugate or if the conjugate itself is impregnated with something else. Even if the claims are amended to clearly recite that the

matrix is impregnated with the conjugate, the claimed device is still obvious over the prior art of record because the specification fails to disclose any advantage of an impregnated matrix as suppose to a coated matrix, and because the specification at page 9, lines 4-6, teaches that the conjugate can be impregnated in the matrix or they can be coated on the matrix, one of ordinary skill in the art can conclude that a matrix having an impregnated conjugate and one having a coated matrix are functionally equivalent.

The argument that Fitzpatrick does not teach an element having a conjugate upstream of the zone cõntaining immobilized analyte is not persuasive because Fitzpatrick clearly teach a sample contact zone having mobilizable, labeled-receptor to the analyte located upstream of a trapping zone containing immobilized analyte (see column 1, lines 46-56).

The argument that Decker teaches away from the instant invention because Decker teaches an assay for determining antigen or antibody from a test sample bound to a solid support is not persuasive. Fitzpatrick discloses the arrangement of the carrier matrix. Decker is cited for their teaching of a universal conjugate and it's advantages. Specifically, Decker teaches that a universal conjugate provides the advantages of amplifying the antigenicity of the bound antibody, thus enabling an increased in binding of the antibody to the antigen.

The argument that Bernstein fails to cure the deficiencies of Fitzpatrick and Decker is not persuasive. The disclosure of Fitzpatrick in view of Decker makes obvious the instant claims for reasons of record and those discussed above. Bernstein is cited for it's teaching of a zone containing an elution agent located upstream of the sample addition zone. Bernstein teaches that a device where all of the reagents, including liquid phase solvents, buffers, etc, necessary to perform the assay are incorporated and requiring only the addition of the sample provides the advantages of a simple test device and improves the assay results because the presence of the analyte can be determined in a sequential form, and because all reagents are flowing simultaneously, the assay time will be shorter for any given results.

Therefore, the claimed assay device is obvious over the prior art of record and for reasons stated above, no claim is allowed.

Conclusion

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

1 May 2003

BAO-THUY L. NGUYEN
PRIMARY EXAMINER